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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,367	08/14/2001	David Duffy	11641/36	6423
23838	7590	02/09/2005	EXAMINER	
KENYON & KENYON 1500 K STREET, N.W., SUITE 700 WASHINGTON, DC 20005			WESSENDORF, TERESA D	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/928,367

Applicant(s)

DUFFY, DAVID

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2004 and 04 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-22,27 and 33-35 is/are pending in the application.
- 4a) Of the above claim(s) 8-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,7,27 and 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1, 6-22, 27 and 33-35 are pending.

Claims 8-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

Claims 2-5, 23-26, 28-32 have been cancelled.

Claims 1, 6-7, 27 and 33-35 are under examination.

Withdrawn rejections and objections:

In view of the amendments to the claims and applicants' arguments, the rejections under 35 USC 112, second paragraph and 103 in view of Matsushita are withdrawn.

Specification

The amendment filed 11/10/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the incorporation of the entire application, S.N. 09/705,187 (the '187 application). The as-filed specification of the

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instant specification simply states to "see" the '187 application. It does not make reference that this is an essential material necessary to support the claims. The presently amended specification now recites that this is an essential material that supports the claims. [Also, the amendment does not accompany a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference (which was not) and that the amendment contains no new matter. 37 CFR 1.57(f).]

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112, first paragraph

Claims 1, 5-7, 27 and 33-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons advanced in the last Office action,

Response to Arguments

Applicants state that the specification has been amended to expressly incorporate subject matter from co-pending U.S.

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application 09/705,187, which was incorporated by reference on page 9 of the specification, paragraph 21. A copy of the application is attached herewith. Specific support for this amendment can be found on page 3, lines 11-14, page 7, lines 18-23, page 8, line 7; page 14, line 1; and page 14, lines 4-11 of U.S. application 09/705,187.

In response, applicants' incorporation of the entire '187 application is not supported in the as-filed specification of the instant specification. The instant specification at page 9 does not recite that the '187 is incorporated by reference. It simply states "...see, e.g., United States Serial No. 09/705,187, entitled Polymer Gel Contact Masks And Methods And Molds For Making Same." MPEP 608.01(p) states that mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973).

The as-filed specification does not provide a description of a method by which a polymer gel contact mask with cavities have a size and an orientation of wells of a 96-well, 384-well and the other recited multiwell. The '187 application does not disclose, as of filing, a polymer gel cavities that is sized

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and orientated corresponding to the size and orientation of the different multiwell. Furthermore, the as-filed instant specification presents a different concept and provides a description of a gasket. It does not recite the use of gasket or polymer gel mask in the alternative as in the presently amended specification. There is no description as to how the polymer gel mask is used such that the method of detecting modification of a target member of a biochemical pathway is obtained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6-7, 27 and 33-35, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruggieri et al (6,630,296) in view of Beebe et al (USP 6,488,872).

Ruggieri et al discloses at col.3, lines 10-40 a method of in which SRK (a class of proteins involved in cell signal transduction pathways such as MAPK pathways) activates inactive

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MAPKK polypeptides, i.e., an MAPKK stimulatory activity. This activity can be direct, e.g., by directly acting upon the MAPKK (e.g., phosphorylating it), or it can be indirect where activation is accomplished by acting upon one or more intermediates which then stimulate MAPKK activity. An MAPKK stimulatory activity means, e.g., that SRK, and polypeptides thereof, activate or stimulate a MAPKK protein kinase activity. MAPKK stimulatory activity can be measured in vivo or in vitro as illustrated in the examples. MAPKK proteins stimulated or activated by SRK include, e.g., MEK. See col. 13, line 2 as to the use of src. In one type of assay, SRK is co-expressed in a cell with an MAPKK; the MAPKK is isolated, and then assayed for kinase activity using an appropriate substrate, e.g., ERK when MEK is used. The amount of stimulatory activity can be determined by measuring the MAPKK kinase activity from cells transfected with and without SRK. MAPKK stimulatory activity can also be measured in cell-based assays. SRK is a member of a cell signal transduction pathway, one activity of which is to activate gene transcription. Expression analysis can be performed conventionally. For example, high-density oligonucleotide chip arrays can be designed to monitor expression. Ruggieri et al at col.16, lines 37-45 recites a 96 well plates as a substrate, inter alia and refers to the

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different U.S. Patents for its method of making. Ruggieri at col. 14, line 10 up to col. 15, line 55, discloses a method of regulating a biological response in which SRK, or a homolog thereof, participates, e.g., by being a participant in the biochemical pathway which leads to the ultimate cellular response. For instance, the invention relates to methods of modulating signal transduction in which SRK is involved. Since such signal transduction can lead to various biological responses, including transcriptional activation of certain genes. The method relates to detecting a protein kinase activity in a SRK polypeptide, or a biologically-active polypeptide fragment thereof. Typically, a method of detecting kinase activity in a SRK polypeptide comprises, reacting a human SRK polypeptide, or a biologically-active polypeptide fragment thereof, and a substrate under conditions effective said SRK polypeptide to phosphorylate said substrate; and detecting said phosphorylation of said substrate. Effective conditions include, e.g., appropriate substrates, ATP, co-factors, etc. For SRK kinase assays, substrates can be, e.g., MAPKKs, such as MEK. Kinase activity means, e.g., the ability of SRK to transfer a phosphate group from a phosphate donor (e.g., ATP) to a phosphate acceptor (e.g., MBP). Ruggieri et al also discloses methods of identifying substrates for SRK kinase activity. SRK

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can be contacted with a test substrate, either in vivo or in vitro, under conditions effective for phosphorylation to occur. After a suitable time, the substrate can be isolated and probed for the presence of a phosphate residue. As mentioned, a preferable method of detecting phosphorylation is to use radioactive ATP. The method further relates to identifying agents which modulate a MAPKK stimulatory activity of a human SRK polypeptide, or a biologically-active polypeptide fragment thereof, comprising, administering a test agent to a cell expressing (1) a human SRK polypeptide, or a biologically-active polypeptide fragment thereof, and (2) an MAPKK polypeptide, under conditions effective for said SRK polypeptide to stimulate protein kinase activity of said MAPKK polypeptide; detecting said protein kinase activity; and identifying whether the test agent modulates said stimulatory activity of said SRK polypeptide by comparing the amount of kinase activity in the presence and absence of the test agent. MAPKK stimulatory means, e.g., the ability of SRK to activate the kinase activity of MAPKK, itself. Such stimulation can be direct or indirect, e.g., where SRK stimulates a factor, which, in turn, stimulates MAPKK. The stimulatory effect is relatively specific for the MAP kinase cascade. The term "administering" as used, means, e.g., any suitable delivery technique, which is adequate to place the

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agent in a location where it can elicit an effect. For example, administering can mean contacting a cell or host in an effective manner with the agent of interest, whereby the agent can modulate the activity of interest. See further cols. 25 and 26, Example 1 and 2 for the specifics of the method. Ruggieri does not disclose the use of polymer gel contact mask as recited.

(Note however, Ruggieri's reference to the different US patents at col.16, *ibid*, which discloses hydrogel. It is disclosed therein that the function of the hydrogel appears to be associated mainly with elimination of nonspecific binding.).

Beebe at col. 6, line 56 up to col. 10, line 38 discloses a polymer gel mask. Beebe discloses that regions in the channel that are to be free of the polymer gel are masked from the reaction (polymerization trigger). The reaction is therefore confined to the desired spatially defined region and any unreacted (polymerization) mixture is rinsed from the channel.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a polymer gel contact mask in the method of Ruggieri as taught by Beebe. The advantage i.e., elimination of unreacted mixture taught by Beebe would provide the motivation to one having ordinary skill in the art to make the modification. Ruggieri provides the same or similar advantage, as known in the cited prior art.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

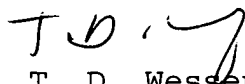
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 8-22 drawn to a non-elected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0812. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
February 7, 2005